Before the
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
FOOD AND DRUG ADMINISTRATION

In re: Food Labeling; Health Claims and Label Statements; Request for Scientific Data and Information	))))	Docket No. 91N-0098 (Fiber and Colorectal Cancer)

SUPPLEMENTAL SUBMISSION OF JULIAN M. WHITAKER, M.D.; PURE ENCAPSULATIONS, INC.; XCEL MEDICAL PHARMACY, LTD.; THE AMERICAN PREVENTIVE MEDICAL ASSOCIATION; AND DURK PEARSON AND SANDY SHAW

Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; XCEL Medical Pharmacy, Ltd.; the American Preventive Medical Association; and Durk Pearson and Sandy Shaw (collectively the "Joint Commenters"), by counsel, hereby submit this supplement to their comments filed on November 22, 1999.

I. ECONOMIC ANALYSIS REVEALS DENIAL OF ACCURATE HEALTH CLAIMS BACKED BY PROOF THAT IS LESS THAN CERTAIN CAUSES HARM TO THE PUBLIC HEALTH AND WELFARE

The Joint Commenters submit to the agency for its an economic analysis on probabilistic health claims performed by Emory University Professor of Economics and Law Paul H. Rubin (Exhibit A). Professor Rubin's curriculum vita is attached as Exhibit B. Professor Rubin formerly served with the Federal Trade Commission and has consulted with and for the Food and Drug Administration.

A. ACCURATE, BUT LESS THAN CERTAIN HEALTH CLAIMS PROVIDE CONSUMERS INFORMATION INDISPENSABLE TO THE EXERCISE OF INFORMED CHOICE

Professor Rubin explains that FDA's historic refusal to allow any health claims to be made in the absence of proof of the underlying diet-disease relationship to a near certainty has produced classic Type II errors (where accurate claims lacking conclusive

proof of nutrient-disease association are suppressed along with demonstrably false claims). Professor Rubin explains that consumers benefit from accurate claims that lack conclusive proof because those claims enable consumers to make market choices based on accurate information in lieu of no information at all or in lieu of fraudulent information. Such claims afford consumers data needed to discern potential benefits of, and to discriminate among, products. Professor Rubin writes:

> [F]or a substance with no exact substitutes and with no harmful effects the tradeoff is between a reduced chance of suffering from some condition and spending some money on a substance that might not be helpful. This is not an issue that a health authority can decide. It is rather an issue of personal choice. If the consumer has valid information about the probability that the substance is helpful, then in a market economy it is appropriate that the consumer decide if the expected benefit is worth the cost. Rational policy would then serve to give the consumer the information needed to make the appropriate decision. There is no sound justification for denying the information to the consumer.

The exercise of reason depends upon access to accurate information. Accurate information consists not only of statements associating a nutrient with a disease when the association is established to a conclusive degree but also of statements that explain that a nutrient-disease association may exist, appropriately disclaimed to reveal the limitations of proof supporting the possible association (e.g., the evidence in support of this claim is inconclusive). In the absence of accurate information, reasoned decision is impossible. Unreasoned decision, or guesswork, involves haphazard elections. Such elections neither maximize consumer welfare (they do not achieve the goals of the consumer; they increase consumer costs in the quest to achieve consumer goals, and they result in mistaken purchases) nor public health (they do not help consumers exercise informed choice in a free market economy). Any decision by this agency to deprive the consumer market of health claims that are accurate but based on a nutrient-disease relationship not

yet established to near certainty will thus redound to the detriment of the public. A decision to deny the claim that is the subject of this rulemaking (disclaimed as the agency reasonably deems fit to ensure accuracy) would have that precise effect.

A. THE PROHIBITION OF ACCURATE, BUT LESS THAN CERTAIN HEALTH CLAIMS EXACERBATES FRAUD IN THE DIETARY SUPPLEMENT MARKETPLACE

In his attached report, Professor Rubin explains that FDA's commission of Type II errors (suppression of health claims that are accurate but are based on nutrient-disease relationships that have not been established to near certainty) exacerbates fraud in the dietary supplement marketplace, thus defeating a central articulated agency purpose for the health claims rule (i.e., avoidance of fraudulent claims). Professor Rubin explains:

> Under current rulings, any message regarding disease risk reducing or treatment properties of supplements is forbidden. Reputable sellers will follow this rule and refrain from providing such information. But less reputable sellers do defy the FDA and set forth exactly the sort of information that is forbidden. Moreover, once a decision is made to violate the FDA's rules, there is no reason to stop with a true statement, nor is there any reason to provide appropriate disclaimers. Rather, a seller who is willing to make illegal claims may make excessive or even totally fraudulent claims, and has no incentive to provide proper disclaimers. Additionally, when a company does provide such untrue or fraudulent messages, there is no market corrective because competitors cannot respond with true information. Thus, it is highly likely that the results of the FDA's policies are less truthful information and more fraudulent or deceptive information in the marketplace.

By depriving the marketplace of health claims that are accurate but are based on nutrient-disease relationships that have not been established, the agency thus produces the ironic effect of fostering an environment where fraud proceeds unchecked and consumers are more apt to be misled. The consequence is a reduction in achievement of consumer goals, an increase in consumer costs, and a loss in public health and welfare.[1]

II. CONSUMER WELFARE IS MAXIMIZED BY ALLOWING CLAIMS THAT ACCURATELY DESCRIBE THE STATE OF SCIENTIFIC EVIDENCE ON NUTRIENT-DISEASE ASSOCIATIONS

If the agency allows the petitioned claim to be made, disclaimed as necessary to avoid a misleading connotation, the Rubin report supports the conclusion that the agency will thereby improve the public health and welfare. It will do so by providing consumers with accurate information indispensable to the exercise of informed choice. Informed choice is the antidote to fraud in the market, as consumers who are informed of the potential benefits of a product are less likely to be misled by those who would make false representations about the product. Accordingly, the Joint Commenters respectfully reiterate their request that the FDA authorize the claim that is the subject of this proceeding with such disclaimer as is, or such disclaimers as are, reasonably necessary to avoid a misleading connotation.

[1] Cost-benefit analysis supports removal of regulatory barriers to market process when doing so results in a net improvement in public welfare. See generally Gary S. Becker, "A Comment on the Conference on Cost-Benefit Analysis," and Richard A. Posner, "Cost-Benefit Analysis: Definition, Justification, and Comment on Conference Papers," in 29 The Journal of Legal Studies 1149-1177 (June 2000). As explained herein and in the Rubin report, public welfare is maximized by removing barriers to the free exchange of accurate information on the potential benefits of dietary supplements.

Respectfully submitted,

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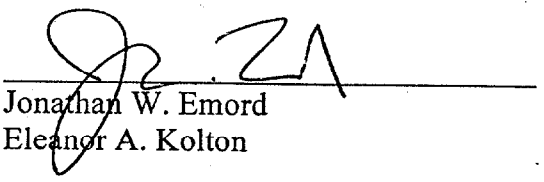

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PROBABILISTIC HEALTH CLAIMS

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In this report, I consider the issue of how best to maximize consumer welfare in the regulation of health claims for which there is some evidence but where the truth of the claim is not "certain."[1] I show that in many circumstances it is appropriate to allow sellers to make such claims, properly qualified. Moreover, I show that in the past the Food and Drug Administration (FDA) has commonly erred by forbidding health claims in circumstances where consumers would have benefited from these claims, and that in fact consumers did benefit when the FDA reversed its policies. I begin with an analysis of decision making under uncertainty.

Decision Making Under Uncertainty

Analysis of decision making under uncertainty is a standard topic in economics and statistics.[2] We begin with some claim that may or may not be true.[3] Then there are two possible errors that a decision maker can make. One error can occur if the claim is false and producers are nonetheless allowed to make the claim.[4] That is, a decision maker (here, the FDA) might err by allowing a false claim. This error is called a "Type I" error. On the other hand, the agency might err by not allowing a true claim. That is, if the claim is actually true but the decision maker does not allow producers to make the claim, this is also an error. This is called a "Type II" error. The possibility of these errors exists for any decision problem; there is no way to avoid the possibility. Statistical

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[1] Actually, contemporary canons of scientific inference suggest that we can never be certain of the truth of a claim, so in a sense this applies to all health claims.
[2] Discussion of this issue is available in virtually all statistics textbooks. For example, see Gary Smith, *Statistical Reasoning*, New York, McGraw Hill, 3rd edition, 1994, Chapters 10-11.
[3] In the general case, the hypothesis that the claim is false is called the "null hypothesis."
[4] In the general case, this is rejecting a true null hypothesis.

decision theory helps us manage the two types of errors, but it cannot eliminate them. The two types of errors are illustrated in Table 1.

Table 1: Types of Errors

	Accept Claim	Reject Claim
If Claim is false	**Type I Error**	**No Error**
If Claim is True	**No Error**	**Type II Error**

The structure of a decision problem is such that if we use a decision procedure that reduces the chance of committing a Type I error, then we of necessity increase the chance of committing a Type II error. That is, if the decision maker tries to be more certain that no one makes any false claims (for example, by requiring a higher standard of proof), then the decision maker also increases the probability that producers are forbidden from making more true claims. For example, if the FDA requires proof of a nutrient disease relationship to a near certainty before a producer is allowed to make a health claim for some substance, then many true claims for substances will not be allowed. This is because there are circumstances in which firms will not find it worthwhile to undertake research to demonstrate the truth of some claims.[5] There is no solution: for a given amount of information, anything that reduces the probability of one type of error increases the probability of the other. This trade-off is inherent in the problem, and cannot be removed.

The only way to reduce the chance of both types of errors is to gather more data. However, this is not a solution. First, during the time when data is being gathered or research is being conducted, useful information about a product's possible utility is not available to consumers. Second, in some circumstances property rights are such that it will not pay for anyone to gather the required data or to undertake the research.

Rational policy making would minimize the total expected costs of the two types of errors. Let P_1 and P_2 be the probabilities of each type of error (determined by the agency's policy) and let C_1 and C_2 be the costs of each type of error. Then the agency

[5] This has to do with the possibility of patenting the substance and so recouping the required investment. For almost all dietary supplements, patenting is not possible and so it will not pay for producers to undertake the research necessary to "prove" a claim, even if they are confident that the research would demonstrate the validity of the claim.

should try to choose P_1 and P_2 to minimize the sum of the expected costs: $P_1C_1 + P_2C_2$. C_1 is the cost of a Type I error – of allowing a claim if it turns out to be false. There are two situations in which a Type I error could have a high health cost. One is if the substance is actually harmful, so that taking the substance itself actually causes health problems. The other situation is one in which there is a better substance available and consumers instead take a less beneficial substance. If neither of these situations holds, then the health cost of a Type I error is low. In these circumstances, the main cost of a Type I error is the money that the consumer might spend for a product with few or no benefits. The health cost of a Type II error is that the consumer might suffer a loss of health benefits that would otherwise be experienced if purchases were made based on the claim.

Thus it is very important to note that for a substance with no exact substitutes and with no harmful effects the tradeoff is between a reduced chance of suffering from some condition and spending some money on a substance that might not be helpful. This is not an issue that a health authority can decide. It is rather an issue of personal choice. If the consumer has valid information about the probability that the substance is helpful, then in a market economy it is appropriate that the consumer decide if the expected benefit is worth the cost. Rational policy would then serve to give the consumer the information needed to make the appropriate decision. There is no sound justification for denying the information to the consumer.

FDA Decision Making

The FDA traditionally places a very high value on not committing a Type I error. That is, the FDA always tries to be sure to a virtual certainty that no one makes a false claim. (This is not always the case because political factors effect FDA decision making and may cause FDA to change its preferred course from time to time.) FDA tries to prevent false claims by requiring a very high degree of certainty before it allows a claim to be made. But this high level of certainty means that many Type II errors will be made. That is, by requiring a high degree of proof to avoid Type I errors, the FDA forces us into a situation where there are too many Type II errors. (The agency acts as if C_1, the cost of

a Type I error, is higher than it actually is.[6]) A Type II error is a failure to make a true claim. Thus, the result of the FDA's decision strategy is that many true claims (which would provide consumer benefits) will not be made, and so consumers will be denied the benefits of the associated products. The mistakes the FDA makes in restricting information and not allowing true and useful claims are systematic, not random. In all cases that have been studied, the FDA has been overly restrictive with respect to allowing claims. Perhaps because of FDA's experience with the high cost of Type I errors for prescription drugs, it consistently puts too high a weight on Type I errors in general, and therefore causes too many Type II errors. I discuss two examples of this decision making below.

The claim at issue here is a claim that:

"Consumption of fiber may reduce the risk of colorectal cancer."[7]

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[6] Note that the cost of making a Type I error by allowing a false claim for a prescription drug may sometimes be very high, and would certainly be far higher than the equivalent cost for a dietary supplement.

[7] I do not claim to be an expert in the health benefits of fiber. However, there is a large body of scientific literature on this issue; see for some examples: Consensus statement on cereals, fibre and colorectal and breast cancers. Proceedings of the European Cancer Prevention consensus meeting. Santa Margheritia, Italy, 2-5 October 1997. Eur J Cancer Prev. 1998 May;7 Suppl 2:S1-83; Consensus meeting on cereals, fibre and colorectal and breast cancers. ECP consensus panel on cereals and cancer. Eur J Cancer Prev. 1997 Dec;6(6):512-4; Global Review of Diet and Cancer Links Available (Review of Food, Nutrition, and the Prevention of Cancer: A Global Perspective. American Institute for Cancer Research, Washington, DC 1998. 670 pages) JAMA. 1997 Nov 26; 278(20) 1650; [No authors listed] Position of the American Dietetic Association: Health implications of dietary fiber. J Am Diet Assoc. 1997 Oct; 97(10)1157-1159; [No authors listed] Primary Prevention of Colorectal Cancer and Polyps: Does Fiber have a Role? Proceedings of a symposium. New York City, New York, USA. December 2, 1997. Am J Med. 1999 Jan 25;106(1A):1S-51S; Byers T. Diet, colorectal adenomas, and colorectal cancer. N Eng L Med. 2000 Apr 20; 342 (16); 1206-7; Caygill CP, et al. Relationship between the intake of high-fibre foods and energy and the risk of cancer of the large bowel and breast. Eur J Cancer Prev. 1998 May;7 Suppl 2:S11-7; Earnest DL, et al. Progress Report: The Arizona Phase III Study of the Effect of Wheat Bran Fiber on Recurrence of Adenomatous Colon Polyps. Am J Med. 1999 Jan 25; 106(1A): 43S-45S; Faivre J, et al. Primary prevention of colorectal cancer through fibre supplementation. Eur J Cancer Prev. 1998 May;7 Suppl 2:S29-32; Faivre J, et al. Chemoprevention of colorectal cancer. Recent Results Cancer Res. 1999;151:122-33. Review; Franceschi S, et al. Italian study on colorectal cancer with emphasis on influence of cereals. Eur J Cancer Prev. 1998 May;7 Suppl 2: S19-23; Freeman HJ. Role of high fibre foods in the prevention of colorectal neoplasia. Can J Gastroenterol. 1999 Jun;13(5):379-80. Review; Garay CA, et al. Chemoprevention of colorectal cancer: dietary and pharmacologic approaches. Oncology (Huntingt). 1999 Jan;13(1):89-97; discussion 97-100, 105; Giacosa A, Hill MJ. Cereals, fibers, and cancer prevention. ECP Consensus Panel. Adv Exp Med Biol. 1999; 472:269-72; Hill MJ. Cereals, cereal fibre and colorectal cancer risk: a review of the epidemiological literature. Eur J Cancer Prev. 1998 May;7 Suppl 2:S5-10; Hill MJ. Cereals, cereal fibre and colorectal cancer risk: a review of the epidemiological literature. Eur J Cancer Prev. 1997 Jun;6(3):219-25; Hill MJ. Mechanisms of diet and colon carcinogenesis. Eur J Cancer Prevent. 1999 Dec; 9 Suppl 1: S95-8; Jacobs LR. Fiber and colon cancer. Gastroenterol Clin North Am 1988 Dec;17(4):747-60; Jacobs LR. Effect of dietary fiber on colonic cell proliferation and its relationship to colon carcinogenesis. Prev Med. 1987; 16:566-571; Jacobs LR. Relationship between dietary fiber and

Forbidding this claim is causing losses to consumer health and well being by putting too high a weight on a Type I error and therefore causing too high a probability of a Type II error. In this situation the cost of a Type I error is low. There is no known health risk from fiber. Taking fiber does not preclude taking other measures to avoid the disease, such as cessation of smoking, exercise, eating a healthy diet, and appropriate early cancer detection and treatment. Taking a supplement is an additional factor in increasing health, not a substitute. The only cost is the actual money cost of the fiber. With sufficient information, consumers would be in the best position to decide if the money cost of the supplement is worth the expected benefit in the form of reduction of the possibility of the disease. The FDA should not deny consumers the information needed to make this decision because doing so reduces consumer welfare

Historical Examples of FDA Decision Making

In general, the FDA puts too much weight on not allowing a false claim and as a result refuses to allow many beneficial true claims. I demonstrate this with respect to two particular historical episodes – health claims for foods and supplements, and direct-to-consumer advertising of prescription drugs. In both cases, the FDA was initially excessively restrictive, and we can see this by examining the impact of a change in FDA policy.

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cancer: metabolic, physiologic, and cellular mechanisms. Proc Soc Exp Biol Med 1986 Dec;183(3):299-310; Jansen MC, et al. Dietary fiber and plant foods in relation to colorectal cancer mortality: the Seven Countries Study. Int J Cancer. 1999 Apr 12;81(2):174-9; Kim YI. AGA technical review: impact of dietary fiber on colon cancer occurrence. Gastroenterology. 2000 Jun; 118(6): 1235-57; Kritchevsky D. Dietary fibre and cancer. Eur J Cancer Prev. 1997 Oct;6(5):435-41; Kritchevsky D. Cereal fibres and colorectal cancer: a search for mechanisms. Eur J Cancer Prev. 1998 May;7 Suppl 2:S33-9; Le Marchand L, et al. Dietary fiber and colorectal cancer risk. Epidemiology. 1997 Nov;8(6):658-65; Macrae F. Wheat bran fiber and development of adenomatous polyps: evidence from randomized, controlled clinical trials. Am J Med. 1999 Jan 25;106(1A):38S-42S; Muller RJ. High Fiber Diet and Colorectal Adenomas., NEJM, 2000; 343: 737; Negri E, et al. Fiber intake and risk of colorectal cancer. Cancer Epidemiol Biomarkers Prev. 1998 Aug;7(8):667-71; Potter JD , McMichael AJ. Diet and cancer of the colon and rectum: a case-control study. J Natl Cancer Inst 1986 Apr;76(4):557-69; Reddy BS. Prevention of Colon Carcinogenesis by Components of Dietary Fiber. Anticancer Res. 1999; 19: 3681-3; Scheppach W, et al. WHO consensus statement on the role of nutrition in colorectal cancer. Eur J Cancer Prev. 1999 Feb;8(1):57-62. Review; Shike M. Diet and lifestyle in the prevention of colorectal cancer: an overview. Am J Med. 1999 Jan 25;106(1A):11S-15S; discussion 50S-51S; Simone CB, Simone NL, CB Simone II. Consumption of fiber reduces the risk of colorectal cancer: A Review. *International J Integrative Med.* July-August 2000. I find this literature persuasive on the point that there is sufficient evidence about fiber and colon cancer risk reduction to allow producers to make the claim, perhaps with appropriate disclaimers.

Health Claims for Foods[8]

Traditionally, the FDA did not allow producers to make health claims for foods. The argument was that if such claims were made, then the food was being marketed as a drug, and the manufacturer was required to have the food go through the new drug approval process. As a result, there were no health claims for foods.[9]

In 1984, the Kellogg company and the National Cancer Institute (NCI) jointly began an advertising campaign aimed at selling Kellogg's All-Bran and also at informing consumers of the health benefits of fiber, a message the NCI had had little success in spreading. The FDA attempted to stop this ad campaign, using the usual argument that the health claim meant that the product should undergo the new drug approval process. However, the Federal Trade Commission (FTC) intervened, and ultimately the FDA backed down and allowed the advertising.

Advertising of the health benefits of fiber led to remarkable results. Consumers learned about the benefits of fiber, and this learning was more important for lower income and less educated consumers, who had not benefited from the NCI information programs.[10] Moreover, manufacturers began to formulate additional brands with fiber. Manufacturers began to advertise that their products were high in fiber and also low in sugar and salt. There was also an explosion of additional health claims and information about other products. Manufacturers of vegetable oil and margarine advertised that their products did not contain cholesterol and were lower in saturated fats and so were less likely to cause heart trouble. Ads promoted Vitamin A for vision. Others discussed calcium and osteoporosis. The American Heart Association and the NCI began to certify certain foods for reduction of heart disease and of cancer. The promotion also caused manufacturers to fund research on the relationship between diet and health and to reformulate products so as to improve their health characteristics.

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[8] Most of this discussion is based on John E. Calfee, *Fear of Persuasion: A New Perspective on Advertising and Regulation*, Washington: AEI Press, 1997.

[9] For many years after significant scientific evidence of the detrimental effect of high dietary cholesterol and saturated fats had been published, the FDA would not even permit food companies to state that their products contained little or no cholesterol or saturated fat.

[10] Pauline M. Ippolito and Alan D. Mathios, "Information, Advertising and Health Choices: A Study of the Cereal Market," *The Rand Journal of Economics*, V. 21, No. 3, Autumn, 1990: pp. 459-480.

Thus, this episode illustrates four relevant points. First, the FDA was hostile to health claims advertising, and for many years suppressed this form of information. Second, when the FDA strictures were relaxed, there was a tremendous increase in the amount of consumer information available. Third, the ability to publicize health claims caused manufacturers to reformulate products and also to do research on additional health properties of foods. Fourth, advertising the health benefits of these healthier foods led consumers changing their diets to eat more of the healthier foods and less of the foods most likely to cause serious health problems. The FDA's pre-1984 policies caused tremendous harm to health of American consumers.

The FDA also refused to allow manufacturers of foods containing folic acid to include on their labels truthful information about the relation between this nutrient and spina bifada or other neural tube birth defects, even though the Center for Disease Control (CDC) had recommended that all women of childbearing age should consume .4 mg of folic acid per day. The CDC made its recommendation in 1992 but as late as 1993 the FDA promulgated a rule prohibiting such claims. This refusal to allow the claim resulted in preventable neural tube defect births.[11]

Direct-to-Consumer (DTC) Advertising of Prescription Drugs[12]

Before 1981, there was little if any DTC advertising. Some firms began such advertising in the early 1980s. In response, the FDA declared a moratorium on such advertising in 1983. After seeking public comment, in 1985 the FDA lifted its ban.[13] However, the form of the regulations was such that there was almost no advertising of pharmaceuticals on television.[14]

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[11] 106 Congress, House of Representatives, Report to Accompany H. R. 2469, Food and Nutrition Information Reform Act of 1997, p. 16.

[12] For a discussion of the history see W. John Thomas, "Direct-to-Consumer Pharmaceutical Advertising: Catalyst for a Change in the Therapeutic Model in Psychotherapy?", *Connecticut Law Review*, Fall, 2000, 209-248.

[13] I was personally involved in this set of events. A paper I co-authored while at the FTC was cited by the FDA in lifting the ad ban. Alison Masson and Paul H. Rubin, "Matching Prescription Drugs and Consumers," *New England Journal of Medicine*, v. 313, (Aug. 22, 1985): pp. 513-515. This paper was the first in the medical literature to enumerate the benefits of DTC advertising. The episode is described in Thomas, op cit.

[14] If an ad indicated both the name of the drug and the condition for which it was to be used, then a "brief summary" (brief only by bureaucratic standards) was required, and it was difficult or impossible to put the brief summary on television. Thus, there were ads listing a condition ("See your doctor for new remedies for baldness") but no drug, or ads naming drugs but no condition.

In 1997, the FDA changed its policy and began to allow DTC advertising on television.[15] As a result, the amount of such advertising has greatly increased. This advertising has provided substantial health benefits – benefits that were denied to consumers for many years by the FDA's previous policy of effectively forbidding such advertising. Analysis of direct to consumer advertising has identified several health benefits. It might appear that physicians have enough information to prescribe drugs for consumers. But there are cases where consumers have information about themselves that may not be available to a physician. This may be because patients do not tell physicians all relevant information, either because they do not know that it is relevant or for other reasons. It may also be that some potential beneficiaries of medication are not in contact with a physician, and so not in a position to receive this information. Thus, benefits accrue because consumers will have some information about themselves that is not readily accessible to a physician. The information known only to individual consumers about their own health status can be combined with information in pharmaceutical ads to better match patients and drugs. Of course, the physician also has information about pharmaceuticals, and she has the final say in prescribing decisions. However direct to consumer advertising will provide greatest benefits in those circumstances where otherwise the consumer would not consult a physician. We may identify several types of benefits from direct advertising.[16]

1. A consumer may suffer some symptoms (e.g., thirst) without realizing that these are symptoms of a disease (e.g., diabetes). A consumer who does not realize that symptoms indicate a disease will not consult a physician and therefore cannot learn in this way that he has a treatable disease. Recent ads for Merck's Proscar indicate that urinary problems may be symptomatic of prostate enlargement, and that there is a non-surgical treatment for this condition. Lamisil ads indicate that discolored or misshapen toenails may be a symptom of toenail fungus. Ads for Lilly's Prozac discuss the symptoms of depression. Ads for Aricept, a product of Eisai and Pfizer, list some symptoms of Alzheimer's disease (e.g., asking repeated questions and trouble using words) that may not be known to everyone. Ads for Prempro and other hormone replacement therapies indicate the signs of menopause,

[15] I testified before the FDA on this issue, in favor or lifting the ban.
[16] This is based on Paul H. Rubin, "Pharmaceutical Advertising as a Consumer Empowerment Device," *Journal of Biolaw and Business,* Forthcoming.

and also that this condition may be associated with osteoporosis. Ads for Rimadyl even provide a guide to symptoms of canine arthritis.

2. Advertising can inform a consumer that a treatment exists for some condition. Without the advertising, the consumer might not know of the existence of the treatment, and so would not consult a physician. An example is Lamisil, Sandoz' medicine for toenail fungus. A consumer might know that he has the condition but not know that there is a treatment. Advertising can indicate that there is an effective treatment for this condition. Similarly, Imitrex advertising tells those who suffer from migraine that there is a new treatment. Tolterodine (Detrol, made by Pharmacia and Upjohn) is used for treatment of patients with an overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence. Advertising has informed consumers about the existence of this drug. Without the advertising, since consumers would not know of the availability of treatment, they would have no incentive to contact a physician. Many consumers believe that this condition is an untreatable aspect of aging, and again, advertising can correct this error.

3. A consumer may have been previously diagnosed with some then untreatable disease for which a new treatment has since become available. Because the consumer believes that the disease is not treatable, or because previous remedies have been ineffective, he will not contact a physician and will not learn about the new therapy. Advertisements can inform him and lead to treatment. For example, Zyrtec advertises that it is an antihistamine that has been approved for children as young as two years old. Many of the ads mentioned here could serve that purpose. Consumers may know they have toenail fungus but not that a treatment is available. Similarly for depression, enlarged prostate, severe social anxiety, and many other conditions. An ad for Enbrel, an injectible treatment rheumatoid arthritis advertises "For people with moderately to severely active rheumatoid arthritis who have not adequately responded to disease-modifying medicines." An ad for Synvisc provides similar information about treatment for osteoarthritis knee pain. This class of advertising is becoming and will continue to become more important as the rate of introduction of new therapies increases.

4. A similar analysis applies to the creation of a new vaccine or preventative for a condition to which some consumers may know themselves to be susceptible. An example is a vaccine for hepatitis B, a disease to which homosexuals are particularly susceptible. Ads

for Wyeth-Ayerst's Premarin and Prempro, and for Ciba-Geigy's Estraderm indicate that these post-menopausal medicines can reduce the chance for osteoporosis, and some of the ads provide information about susceptibility to this condition. An advertising campaign for Nolvadex, the Zeneca-Roche preventative for breast cancer, suggests that women contact their doctors for a "Breast Cancer Risk Assessment Test."

Ads for anti-cholesterol drugs such as Pravachol, Zocor and Lipitor can warn consumers of the dangers of high cholesterol. Such ads may be very useful. Several studies have shown that this class of drugs can reduce cardiac deaths by 24 percent to 42 percent. Only about one-third of the 13 million Americans with heart disease symptoms are now taking them, and an additional 16 million with no symptoms but with significantly elevated cholesterol levels are not being treated. Advertising can induce many of these people to seek medical care. After advertising for these drugs began 8.8 million people sought treatment in 1997 for cholesterol-related therapies, up from 7.2 million in 1996, perhaps in part as a result of the ad campaign for Pravachol.

5. A new remedy with reduced side effects may become available. Advertising can provide benefits in two cases. Consumers who do not know that symptoms they are experiencing are side effects, and so would not ask a physician about them, may learn from ads that there are alternatives without these side effects. Consumers who have ceased treatment because of side effects, and so are not seeing a physician, may begin treatment again if they learn of therapies that do not impose the same side effects. An example is impotence caused by some antihypertensives. Some consumers may not know that the condition is drug related; others may have stopped therapy because of the condition. Either class of consumers can benefit from ads indicating that a treatment with reduced side effects is available.

6. A medication may simply be available that is more convenient than existing medications. For example, Searle advertises Daypro as an arthritis medicine that can be taken only once a day. Zyrtec advertises that it begins working within one hour. Depo-Provera is advertised as a method of birth control that does not require daily medication. Alza advertises Ditropan XL as a remedy for overactive bladder that can be taken once a day. Rhone-Poulenc Rorer advertises CombiPatch as an estrogen replacement therapy that is in the form of a patch. AstraZeneca promotes Prilosec as a once a day heartburn remedy.

Pfizer's Zithromax is advertised as an antibiotic for childhood ear infections that can be taken once a day for five days. This ad capitalizes on the well-known potentially harmful tendency for patients or parents to stop medication after symptoms have disappeared.

A physician might not be aware that the less convenient form is a problem for a particular consumer, and so might not suggest the alternative form of the medicine. Alternatively, a consumer might have stopped using the medication because of the inconvenience, and so not be in contact with a physician at all. Learning of the more convenient form can then induce the consumer to see a physician and reenter treatment. Thus, direct advertising in this instance can be quite useful, both for satisfying consumer preferences regarding forms and for improving health if the new form leads to additional use of the medicine.

7. Advertising can inform consumers that some conditions are medically treatable. Consumers might not think of conditions treated by some medicines as medical, or might not know of the availability of treatments. A leading example is the advertising of Viagra, the impotence remedy. Other examples include ads for Propecia and Rogaine, hair loss treatments, and for aids in smoking cessation such as Glaxo's ads for Zyban. Rogaine also advertises specifically for women. Ortho's Renova is advertised as a prescription skin treatment for fine wrinkles and brown spots. Ortho advertises that its Tri-Cyclen birth control pill also treats acne.

8. Some patients may be embarrassed to discuss some conditions with a physician. One example is urinary incontinence, treatable by Detrol; ads have tried to remove this embarrassment. Similarly, ads for Viagra indicate that "There is no need to be embarrassed or ashamed when discussing ED [erectile dysfunction] with your doctor. He or she has probably diagnosed and treated ED many times." In another Pfizer ad (which is not product specific), Robert Dole is quoted as saying "It may take a little courage to ask your doctor about erectile dysfunction." Such advertising can induce patients to provide information to physicians that they otherwise might not be willing to contribute. These ads and others may induce consumers more generally to be willing to discuss certain conditions with friends and family members as well as with physicians.

These benefits are now available to consumers. However, the previous policy of the FDA, lasting from 1985 to 1997, of not allowing ads on television had the effect of

denying these benefits and therefore greatly reduced the health of American consumers. Similarly, potential disease risk reduction and treatment benefits from dietary supplements are locked out of the marketplace. Consumers are thereby deprived of information which would be useful for purchase of products that would increase health.

Fraud

So far, the argument has been that the FDA's policies deny consumers information useful for improving their health. But the issue may be worse. It is highly likely that the policies actually lead to consumers having false or incorrect information.

Under current rulings, any message regarding the disease risk reducing or treatment properties of supplements is forbidden. Reputable sellers will follow this rule and refrain from providing such information. But less reputable sellers do defy the FDA and set forth exactly the sort of information that is forbidden. Moreover, once a decision is made to violate the FDA's rules, there is no reason to stop with a true statement, nor is there any reason to provide appropriate disclaimers. Rather, a seller who is willing to make illegal claims may make excessive or even totally fraudulent claims, and has no incentive to provide proper disclaimers. Additionally, when a company does provide such untrue or fraudulent messages, there is no market corrective because competitors cannot respond with true information. Thus, it is highly likely that the results of the FDA's policies are less truthful information and more fraudulent or deceptive information in the marketplace.

Summary

The FDA prides itself on being a scientific agency, and requiring scientific proof for any claims. However, it is unwilling to perform a scientific analysis of its own policies. If it did so, it would find that its information policies, with an over-reliance on deterring Type I errors and insufficient attention to Type II errors, lead to substantial consumer harm. This was true of policies in the past which forbade promotion of health claims for foods, and policies which kept DTC advertising off of television. It is equally true of policies that prevent manufacturers of dietary supplements from informing consumers of the state of knowledge about the disease risk reducing and treatment effects of these supplements. Such information, with proper disclaimers, could greatly increase the health of Americans.

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EDUCATION

Ph.D., Economics, Purdue University, 1970
B.A., University of Cincinnati, 1963 (Honors)

PROFESSIONAL EXPERIENCE

ACADEMIC

Professor of Economics and Law, Emory University, beginning 1999; Professor of Economics, 1991-1999; Acting Chair, Economics, 1993-94.
Adjunct Professor: VPI, 1984; George Washington University Law Center, 1985-89.
Professor, Baruch College and the Graduate Center, CUNY, 1982-83.
Assistant, Associate and Full Professor of Economics, University of Georgia, 1968-82.

NONACADEMIC

Vice President, Glassman-Oliver Economic Consultants, 1987-1991.
Chief Economist, U.S. Consumer Product Safety Commission 1985-87 (Senior Executive Service).
Director of Advertising Economics, Federal Trade Commission, 1983-85.
Senior Staff Economist, President's Council of Economic Advisers, 1981-82.

ADDITIONAL PROFESSIONAL AFFILIATIONS

Adjunct Scholar: American Enterprise Institute; Georgia Public Policy Foundation; Cato Institute, 1992-1998.
Editor In Chief: *Managerial and Decision Economics.*

RESEARCH AND TEACHING AREAS

Law and Economics (Economics Departments, Law Schools, and Practicing Attorneys); Industrial Organization and Antitrust; Transactions Cost Economics; Government and Business (Economics and MBA Students); Public Choice; Economics of Advertising and Safety; Regulation and Cost-Benefit Analysis; Price Theory; Law in Post-Communist Economies; Biological Evolution and Economics.

PROFESSIONAL RECOGNITION

Over 1300 citations to published work in *Social Science Citation Index*; about 60-75 per year.

"Why Is the Common Law Efficient?" *Journal of Legal Studies*, 1977, over 250 citations; Reprinted seven times, in English, Spanish and French.

"Self Interest, Ideology and Logrolling in Congressional Voting," *Journal of Law and Economics*, 1979, with James Kau, over 160 citations; Reprinted once.

"The Theory of the Firm and the Structure of the Franchise Contract," *Journal of Law and Economics*, 1978, over 120 citations; Reprinted once.

Listed in *Who's Who in Economics, A Biographical Dictionary of Major Economists*, Second Edition, edited by Mark Blaug, Cambridge: MIT Press, 1986; Third Edition, edited by Simon James and Mark Blaug, Hants, UK: Edgar Elgar Publishing, Limited, 1998. These volumes include the 1000 most cited living and 400 deceased economists. Living econmists citations determined from the *Social Sciences Citation Index.*

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Grants and Fellowships: Emory University International Travel Fund, 1998; 2000; Emory University Research Committee, 1997; William H. Donner Foundation, 1997-98; Pfizer, 1997; IRIS (University of Maryland, funded by USAID), 1992-93; Paul Oreffice Fund, AEI, 1993; Liberty Fund, 1979; CUNY, 1983.

Fellow, Public Choice Society

Member, Institute of Justice task force on "Consumer Freedom"

Asked to write entries for *Encyclopedia of Law and Economics* and for *New Palgrave Dictionary of Economics and the Law.*

Senior lecturer, World Bank Conference on Private Sector Development, Trest, Czech Republic, November 1994.

First Vice-President, Southern Economics Association, 1994-1996

Vice-President, Georgia Chapter, National Association of Scholars, 1994-2000.

Chairman's Award, Consumer Product Safety Commission, 1987.

Managing Business Transactions, 1990; paperback, 1993

Reviews: *Journal of Economic Literature*, June, 1992, by David Kaserman, 900-1; *Southern Economic Journal*, July, 1992, by Dwight Lee, 131-132; *Managerial and Decision Economics*, January, 1993, by Gregory Dow, 91-93; *Across the Board*, January, 1991, by Shlomo Maital; *Booklist*, November, 1990; *Journal of Business Communications*, 1993, by Donald P. Rogers, p. 84-85; *Sloan Management Review*, Winter, 1991; *Personal Selling Power*, March, 1991; *Manageris* (French), 1994, by Bernard Sinclair-Desgagne.

Several course adoptions; selected by the Executive Book Club.

Guest editor, special issue of *Managerial and Decision Economics*, March 1993, stimulated by *Managing Business Transactions.*

Tort Reform by Contract, reviewed, *Journal of Legal Economics*, July 1998, by Thomas Irleand, 96-98.

PUBLICATIONS

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Written:

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2. *Business Firms and the Common Law,* Praeger, 1983
3. *Managing Business Transactions: Controlling the Costs of Coordinating, Communicating, and Decision Making,* Free Press, Foreword by Oliver Williamson, 1990; paperback, 1993.
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58. "Mitigating Agency Problems by Advertising, With Special Reference to Managed Care," *Southern Economic Journal*, July 1999, 39-60, with Joel Schrag (Lead regular article).
59. "The State of Nature and the Evolution of Political Preferences," *American Law and Economics Review*, forthcoming.
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61. "Group Selection and the Limits to Altruism," *Journal of Bioeconomics*, Forthcoming.
62. "Hierarchy," *Human Nature*, Vol. 11, No. 3, 2000, 259-279, Forthcoming.
63. "Does Ethnic Conflict Pay?," *Politics and the Life Sciences*, Forthcoming.

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3. "Constitutional Limits on the Role of the Federal Government in the Economy," in Aronoff and Ward, editors, *The Future of Private Enterprise,* Atlanta, 1984, with Jerry Jordan, 111-130.
4. "Private Mechanisms for the Creation of Efficient Institutions for Market Economies," in Laszlo Somogyi, editor, *The Political Economy of the Transition Process in Eastern Europe,* Edward Elgar, 1993.
5. "From Bad to Worse: Recent FDA Initiatives and Consumer Health" in Richard T. Kaplar, editor, *Bad Prescription for the First Amendment: FDA Censorship of Drug Advertising and Promotion,* Media Institute, 1993.
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9. "Pricing, Entry, Service Quality, and Innovation Under A Commercialized Postal Service: A Comment," in Gregory Sidak, editor, *Governing the Postal Service*, AEI Press, 1994.
10. " FDA Advertising Restrictions: Ignorance is Death," in Robert Higgs, editor *Hazardous to Our Health? FDA Regulation of Health Care Products,* Independent Institute, 1995.
11. "Economic Analysis of Deception Standards," Introduction to *Advertising Law Anthology,* July-December, 1994, xv-xxv.
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13. "Costs and Benefits of the MFJ," Introduction to *Deregulating Telecommunications: The Baby Bells Case for Competition*, Wiley, 1995, with Richard Higgins.
14. "Courts and the Tort-Contract Boundary in Product Liability," in Frank Buckley, editor, *The Fall and Rise of Freedom of Contract*, Duke University Press, 1999, 119-139.
15. "Ideology" in William F. Shughart II and Laura Razzolini, editors, *Elgar Companion to Public Choice*, Edward Elgar, in press.
16. "Ignorance is Death: The FDA's Advertising Restrictions," in Roger D. Feldman, Editor, *American Health Care: Government, Market Processes, and the Public Interest*, The Independent Instuitute and Transaction Publishers, 2000, 285-311.

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2. Maxwell Stearns, editor, *Public Choice and Pubic Law: Readings and Commentary,* Anderson Publishing Co., 1997.
3. Kenneth Dau-Schmidt and Thomas Ulen, editors, *Law and Economics Anthology*, Anderson Publishing Co., 1998.
4. Richard Posner and Francesco Parisi, editors, *The International Library of Critical Writings in Economics, Law and Economics,* Edward Elgar, 1997.
5. Michael Arnheim, editor, *The International Library of Essays in Law and Legal Theory: The Common Law*, Dartmouth Publishing Co., 1994.
6. Andres Roemer and Hugo Garduno, Editors, *Law and Economics: A Literature Survey (Derecho y Economía: una revisión de la literatura*), Fondo de Cultura Económica, Mexico, 2000, in press.
7. Louis Vogel, Law and Economics (in French), in press.

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8. Andreano and Siegfried, editors, *The Economics of Crime,* Wiley, 1980.
9. Alper and Hellman, editors, *The Economics of Crime: A Reader*, Simon and Schuster, 1988.

10. "A Paradox Regarding the Use of Time," in J. King, editor, *Readings in Labor Economics,* Oxford University Press, 1980.
11. "The Impact of Labor Unions on the Passage of Economic Legislation," with J. Kau, in J. Baderschneider, editor, *The Collective Bargaining Process,* BPI, 1982,
12. "A Socioeconomic Model of National Olympic Performance," in J. Loy, et al., editors, *Sport, Culture, and Society: A Reader on the Sociology of Sport*, Lea and Febinger, Philadelphia, with R. Grimes and W. Kelly, 1982.
13. "Matching Prescription Drugs and Consumers" with Alison Masson, in *Chemical Dependency*, Greenhaven Press, 1989.
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16. "Self Interest, Ideology and Logrolling in Congressional Voting," in Charles Rowley, editor, *Library of Critical Writings in Economics: Public Choice Theory,* Edward Elgar Publishing Co., 1992, with James Kau.
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20. "Promises, Promises: Contracts in Russia and Other Post-Communist Economies," in Charles Rowley, editor, *Classical Liberalism and Civil Society,* Edward Elgar and the Locke Institute, 1998.
21. "The Theory of the Firm and the Structure of the Franchise Contract," in Martin Carter, Mark Casson and Vivek Suneja, editors, *The Economics of Marketing,* Edward Elgar, 1998.
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REVIEWS, ENCYCLOPEDIA ENTRIES, OP-ED AND MAGAZINE ARTICLES, TRIBUTES, MISCELLANEOUS PUBLICATIONS

Book Reviews

1. Richard Nelson and Sidney Winter, *An Evolutionary Theory of Economic Change*, in *Journal of Political Economy,* August 1983.
2. William Shughart, *Antitrust Policy and Interest Group Politics,* in *Regulation,* Winter, 1991.
3. Richard McKenzie and Dwight Lee, *Quicksilver Capital,* in *Regulation,* Summer, 1991.
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5. Gerald W. Scully, *Constitutional Environments and Economic Growth,* in *Cato Journal,* Fall, 1992.
6. Nicholas Mercuro, Editor, *Taking Property and Just Compensation: Law and Economics Perspectives on the Takings Issue* in *Public Choice*, 1994.
7. Donald Drake and Marian Uhlman, *Making Medicine, Making Money* in *The Journal of Research in Pharmaceutical Economics,* 1995, 103-107 and in *Journal of Pharmaceutical Marketing and Management,* 1995, 47-49.
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OTHER PROFESSIONAL ACTIVITIES

PARTICIPATION IN PROFESSIONAL MEETINGS

American Association of Law Schools, 1985.
American Economics Association/Allied Social Science Associations, 1979, 1980, 1981, 1984, 1993, 1994, 1995, 1996, 1997, 1998, 1999.
American Law and Economics Association, 1993, 1994, 1995, 1996, 1997, 1998, 1999.
Association for Politics and the Life Sciences, 1999.
Canadian Law and Economics Association, 1999.
Econometric Society, 1970, 1971, 1974, 1975, 1977, 1978; European Meetings, 1978.
European Law and Economics Association, 1993, 2000.
International Society for Human Ethology, 2000.
International Society for New Institutional Economics, 1998.
Public Choice Society, 1977, 1978, 1979, 1980, 1981, 1983, 1985, 1989, 1992, 1993, 1994, 1996, 1998, 1999.
Society for Evolutionary Analysis in Law, 2000.
Southern Economic Association, 1971, 1976, 1977, 1978, 1979, 1980, 1981, 1984, 1985, 1987, 1991, 1993, 1994, 1995, 1996, 1997, 1998.
Southern Political Science Association, Invited Panel, 1998.
Western Economic Association, 1974, 1975, 1984, 1985, 1988, 1996, 1997.

CONFERENCE ORGANIZED

"Economics of Consumer Protection," Georgetown University, Continuing Legal Education, 1985.

INVITED PRESENTATIONS AND CONFERENCES

Presentations at Universities

Arizona State University, 2000; Auburn University, 1978, 1996; Berkeley, 1984; Boston University, 1984; Carnegie-Mellon, 1982; Case-Western Reserve University, 1986; CIRANO (Montreal), 1996; Clemson University, 1993; Columbia University, 1998; Cornell University, 1998; Duke University, 1981; Emory University, 1981; Florida State University, 1998; George Mason University, 1983, 1985, 1989, 1990, 1992, 1993, 1994, 1995, 1997, 1998; Harvard University, 1993, 1995; Hoover Institution, 1983; Lund University (Sweden), 1992; Montana State University, 1998; McMaster University, 1983; NewYork University, 1998; Northwestern University, 2000; Purdue University, 1991; Stanford University, 1995; Texas A & M, 1985; University of Chicago, 1978, 1979; University of Florida, 1989; University of Georgia, 1996; University of Kansas, 1995; University of Miami, 1979; University of Michigan, 1987; University of Pennsylvania, 1993; University of Toronto, 1984, 1995; Virginia Polytechnic Institute, 1983; Washington University, 1991, 1993; Western Ontario, 1984; York University, 1984.

Non-Academic Presentations

Federal Trade Commission, 1983; Cato Institute, 1985, 1990, 1991; U.S. Department of Justice, Antitrust Division, 1986, 1988, 1995; National Association of Business Economists, 1988; Brookings Institution, 1986; American Medical Writers-Pharmaceutical Advertising Association, 1986; National Library of Medicine, 1986; American National Standards Institute, 1986; Jefferson Society, 1986; Drug Information Association, 1991; U.S. Commodities Futures Trading Commission, 1991, Distinguished Speaker, 1992; U.S. Chamber of Commerce, Washington, 1991; Milken Institute, 1992; Food and Drug Law Institute, 1992; Institute for International Research, 1992; Heritage Foundation, 1992; American Enterprise Institute, 1992, 1993, 1994, 1995; Coalition of Healthcare Communicators, 1992; Independent Institute, 1993, 1994; Political Economy Research Center, 1994; Ad-Hoc Committee on Pharmaceutical Economics, 1997; Employer's Managed Health Care Association, 1999; Mercatus Center (Capitol Hill), 2000.

Invited Conference Attendance

Economics of Regulated Utilities, University of Chicago, 1975; Legal Institute for Economists, University of Miami, 1977; Private Alternatives to the Judicial System, University of Miami, 1978; Toward Liberty, VPI, 1978; Evolutionary Theory in Law and Economics, University of Miami, 1980; Guest, Nutter Memorial Lecture, Hoover Institution, 1981; Regulatory Authorities, Corporate Privacy, and the Corporate Attorney, Emory University, 1981; Carnegie Conference on Political Economy, Pittsburgh, 1982, 1983, 1984; Constitutional Economics, Heritage Foundation, 1982; Perspectives on Entrepreneurship, Political Economy Research Center, Denver, 1984; Critical Issues in Tort Law Reform, Yale, 1984; Valuing Health Risks, National Academy of Sciences, 1987; The Calculus of Consent After 20 Years, Santa Cruz, 1988; Political Economy Forum, Political Economy Research Center, Bozeman, Montana, 1990, 1998; Malpractice Reform, American Enterprise Institute, 1992; Health Care Policy and Regulation Workshop, Rutgers, 1994; Franchising, University of Michigan, 1994; Workshop on the Evolution of Utilities and Utility Functions, University College, London, 1997; Evolution and Legal Theory, Georgetown University, 1999.

OUTSIDE PROMOTION AND TENURE REVIEWS: Baruch College, CUNY; Brigham Young; Cornell; George Mason; George Washington; Florida State; Pennsylvania State University at Erie; University of Alabama; University of Kansas; University of Southern California; University of Minnesota; Vanderbilt.

DOCTORAL COMMITTEES CHAIRED:

Susan Griffin, Emory, 1994, (Center for Disease Control); Todd Merolla, Emory, 1995; Kristine Principe, Emory, 1996; Raymond Atkins, Emory, 1998 (J.D., George Mason; Covington and Burling); John Yun, Emory, 1999 (Federal Trade Commission); Kari Jones, Emory, 1999 (Univeristy of Georgia); David Prince, 2000 (J.D., Univeristy of Michigan; Simpson, Thacher and Bartlett).

EDITORIAL

Editor-in-Chief

Managerial and Decision Economics, since 1994; editor, Special issue, "Transactions Costs and Management," 1993.

Editorial Boards

Public Choice; Regulation; Journal of Bioeconomics; Journal of Research in Pharmaceutical Economics; Journal of Real Estate Finance and Economics.

Referee

National Science Foundation; Research Council of Canada; *American Economic Review; American Journal of Political Science; American Law and Economics Review; American Political Science Review; Annals of Regional Science; Cato Journal; Contemporary Policy Issues; Eastern Economic Journal; Economic Inquiry; Economic Journal; Economics of Governance; Emory University Law Review; European Journal of Law and Economics; International Regional Science Review; International Review of Law and Economics; Journal of Corporate Finance; Journal of Economic Behavior and Organization; Journal of Economics and Business; Journal of Economics and Finance; Journal of Labor Research; Journal of Law and Economics; Journal of Law, Economics, and Organization; Journal of Legal Studies; Journal of Marketing; Journal of Political Economy; Journal of Public Economics; Journal of Real Estate Finance and Economics; Journal of Social and Biological Structures; Journal of the American Real Estate and Urban Economics Association; Managerial and Decision Economics; National Tax Journal; Politics and the Life Sciences; Public Choice; Public Finance Quarterly; Quarterly Journal of Economics; Review of Regional Studies; Social Science Quarterly; Southern Economic Journal*; Marketing and Public Policy Conference, 1995.

CONSULTING

ANTITRUST, INCLUDING MERGERS AND ACQUISITIONS

Appelton Papers; ARCO; Barclays Bank and Visa; Broadcast Music Inc.; Browning-Ferris Industries; Campbells; Coca-Cola Bottling Company of the Southwest; College Football Association; Columbian Chemical Company; Dresser Industries; First Hawaiian; Georgia-Pacific; General Motors; Juki; Kodak and Fuqua; Levi Strauss; McKesson; National Soft Drink Association; Nederlander; *Newsday; Olivetti*; Professional Golfers Association; Real estate industry, market definition; Regional Bell Operating Companies; Roppe; Sara Lee; Scripps; SmithKline-Beckman; Southern Natural Gas; Thomson; United Airlines; West Point Pepperell.

OTHER MATTERS

Alamo Car Rental; Cemex; Ciba-Geigy; Dial Corp; Drug Emporium; Emerson Electric; for Hernando de Soto, on property rights in the informal sector of the Peruvian economy, cited in *The Other Path*; Ford Motor Company; National Propane Gas Association; Pfizer; Physicians Weight Loss; R.J. Reynolds, on advertising matters; Hedonic damages, several cases; U.S. Sentencing Commission; Texans Against Censorship, Inc.

TESTIMONY

In the U. S. District Court, Eastern District of Texas, on lawyer advertising, for Texans Against Censorship, Inc., 1995.

For defendants in tort liability litigation, criticizing use of "hedonic" damages.

Congressional Committee, pro bono testimony, on recall of All Terrain Vehicles, 1988.

For the New York Power Authority, before the Nuclear Regulatory Commission on costs and benefits of the Indian Point Nuclear Reactor, 1983.

For the Pharmaceutical Manufacturers Association, before the Health Committee of the Georgia Senate, on bills to regulate pharmaceutical prices, 1994; 1995.

Before the Food and Drug Administration, on direct-to-consumer promotion of pharmaceuticals, sponsored by the Progress and Freedom Foundation, 1995.

For the State on New Mexico, regarding taxation of franchising, in an administrative proceeding.

AFFIDAVITS FILED

Airline Antitrust Litigation, regarding the value of the settlement; cited favorably and found "credible" in *Order* of Marvin H. Shoob, Senior U.S. District Court Judge, 1992

Motion of Bell Atlantic, Bellsouth, NYNEX and Southwestern Bell to vacate the Modified Final Judgment in the AT&T Case, 1994.

For Hoechst Celanese Corporation, in the class action regarding polybutylene plumbing, in Chancery Court for Obion County, Tennessee, regarding the fairness of the $950 million settlement.

Willmann et al. v. GTE, U.S. District Court, Southern District of Illinois, class action regarding "Inside Wire", on the fairness of the settlement; cited favorable and found "credible" by the Court.

Folkerts et al. v. Illinois Bell Telephone Company and Todt et al. v. Ameritech, class action suits regarding "inside wire", on the fairness of the settlements. (There are no decision as yet in these matters; I had previously worked on liability and damage issues for plaintiffs.)

Eller Media v. City of Milwaukee, for Eller Media on the effects of advertising on smoking in First Amendment suit regarding City of Milwaukee ordinance restricting tobacco advertising on billboards. Settled.

Julian M. Whitaker, M.D. v. Donna E. Shalala, Secretary, regarding first amendment issues in the labeling of Saw Palmetto, a dietary supplement, June 8, 2000